

## REMARKS

By the present Amendment, claims 25 and 26 are amended to correct a typographical error in the preamble of each claim. This Amendment should be entered, even though after final rejection, since it does not raise new issues and places the claims in better form. This leaves claims 12-26 pending in the application, with claims 12 and 24 being dependent.

### Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 14 stands rejected under 35 U.S.C. § 112, second paragraph, on the ground that “a specified over-pressure” is vague and indefinite.

As clearly indicated in the Remarks of the previously filed Amendment, as well as the application specification, this phrase means a pressure over ambient pressure as would be readily recognized by a person skilled in this art. In view of the specified and recognized definition, the term is not vague or indefinite.

Additionally, such terminology is used in U.S. Patent Nos. 7,200,975 and 7,401,417, as well as other patents, demonstrating that such terminology is acceptable. U.S. Patent No. 7,200,975 lists as the Examiner, the same Examiner as involved in this application.

Accordingly, reconsideration and withdrawal of the rejection of claim 14 as being indefinite is requested.

### Rejections Under 35 U.S.C. §§ 102 and 103 Based on Hansen German Patent

Claim 12 is directed to a method and Claim 24 is directed to a device for producing and filling containers wherein a sterile barrier covers the filler opening at least from the formation time of the filler opening to the filling of the tube, and wherein a sterile medium is conveyed at least in the direction of the filler opening from the sterile barrier by a media delivery device.

Such covering of the filler opening in combination with the conveying of the sterile medium in the direction of the filler opening is not disclosed or rendered obvious by any of the cited patents.

Claims 12-14 and 17-25 stand rejected under 35 U.S.C. §102 as being anticipated by DE 10 063 282 C2 to Hansen, with Pub. No. US 2004/0065983 A1 used as a translation thereof. The Hansen German patent is cited for disclosing the basic blow-filling-sealing method and apparatus. The sterile barrier 23 is interpreted as covering the opening of the tube from the time of its formation to its filling, with its heating of the surrounding air creating a sterile medium that is moved in the direction of the fill opening. Relative to claims 13 and 14, a pressure differential is viewed as being inherent. Relative to claims 17 and 25, the barrier 23 is viewed as a plate-shaped cover element that functions, as allegedly claimed.

Claims 15, 16 and 26 stand rejected under 35 U.S.C. §103 as being unpatentable over the Hansen German patent in view of Pub. No. US 2002/0159915 A1 to Zelina. The Zelina publication is cited for a sterile medium being hydrogen peroxide and the use of a suction device. In support of the rejection, it is alleged that it would be obvious to use the Zelina sterile medium and vacuum device in the Hansen method and apparatus.

Relative to the Hansen patent, the air flow described as being away from the container opening is allegedly not supported by the disclosure of that patent. However, the fact that hot air rises, due to its lower density or weight relative to the surrounding colder air, provides clear and adequate support. No response or any comments adequately refute this analysis or satisfy the burden of showing inherency. The alleged expansion of the heat in all directions is not supported by any analysis or evidence. The covering by the plate 23 of the cited Hansen German patent does not involve the delivery of a sterile medium, as claimed.

Since the Hansen German patent fails to disclose or render obvious conveying a sterile medium in the direction of the filler opening from a sterile barrier by a media delivery device or a media deliverer coupled to the sterile barrier for conveying sterile medium in a direction of the filler opening, the pending claims are not anticipated by or rendered obvious in view of this Hansen German patent, considered alone or in any obvious combination with the other cited patents.

Relative to the proposed combination of the German patent and the Zelina patent, such patents are non-analogous and no adequate reason is provided to support the proposed combination as being obvious.

#### Rejection Under 35 U.S.C. § 102 over Japanese Patent Publication

Claims 12-14, 17, 20 and 22-25 also stand rejected under 35 U.S.C. §102 as being anticipated by Japanese Patent Publication No. 60049919 A to Furui Koichi. The Furui Koichi patent publication is cited as disclosing a blow-mold-fill-seal method and apparatus for forming a container where a sterile barrier 12 is allegedly provided to cover the tube opening from its formation to its filling and has a sterile medium in the form of aseptic air pressure that is moved in the direction of the filler opening. The remaining limitations of the dependent claims also are indicated as being within this Japanese patent publication.

Submitted herewith is an English Language Translation of the Japanese patent publication. As described in this translation and illustrated in the drawings thereof, a parison 6 is delivered from the head 5 of an extruder 1 between the dies 8 of mold 3. As the mold dies are closed, the parison is cut by cutter 9 to form a filler opening. After the cutting, the mold 3 moves to the blowing and injection mandrel station beneath the filling head 10 of the molding and filling device 2. Only after the mold has been moved under the blow molding and filling head 10

located in the sterile chamber 12 is the filler opening previously formed by the cutter 9 covered by that sterile chamber. At the cutting operation under the extruder head 5 and during the movement of the mold with the opened parison therein to its position under blow molding and filling head 10, the formed filler opening in the parison 6 is exposed to contaminants until it reaches its final position under mandrel 11 and sterile chamber 12.

In contrast, claims 12 and 24 require that the sterile barrier cover the filler opening in the tube from its formation. Since the filling opening in the Japanese patent publication is not covered by the sterile barrier from the time of its formation to its filling, the subject matter of claim 12 or claim 24 is not anticipated or rendered obvious by the cited Japanese patent publication.

Claims 13, 14, 17, 20 and 22-25, being dependent upon claim 12 or 24, are also allowable for the above reasons. Moreover, these dependent claims are further distinguishable by the additional limitations recited therein.

Particularly, the Japanese patent publication does not provide a sterile barrier in the form of a plate-shaped cover element of claim 17. The temperature range of claim 23 is also not disclosed, since temperatures of only 138° C and below are disclosed in the Japanese patent publication. Claim 25 is further distinguishable by the barrier being a plate-shaped cover element with plural outlet ports, which plate-shaped element and plural outlet ports are not disclosed in the Japanese patent publication that only appears to have one outlet port.

In view of the foregoing, claims 12-26 are allowable. Prompt and favorable action is solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Mark S. Bicks", written in black ink.

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